

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrew McMichael, Adrian V.S. Hill, Sarah C. Gilbert, Jörg Schneider, Magdalena Plebanski, Tomas Hanke, Geoffrey L. Smith and Tom Blanchard

Application No.: 10/686,943

Group: 1648

Filed: October 16, 2003

Examiner: Not Yet Assigned

Confirmation No.: 4585

For: Methods and Reagents for Vaccination Which Generate a CD8 T Cell Immune Response

| CERTIFICATE OF MAILING OR TRANSMISSION | |
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| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on: | |
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| <i>Jeanine Busby</i> | |
| Typed or printed name of person signing certificate | |

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

☒ Enclosed herewith is form PTO-1449:

☒ Copies of the cited references are enclosed.

☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

☒ Copies of the cited references are enclosed (AZ, AR3, AV3, AY4, AZ4, AR5, AS5, AX5, AY5, AS6, AT6, AS7, AU7, AV7, AX7, AV8-AZ8, and AR9-AZ9; AR10) except those entered in prior application, U.S. Application No. 09/454,204, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.

☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:

☐ the explanation provided on the attached sheet.

☐ the explanation provided in the Specification.

☐ submission of the enclosed International Search Report.

☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

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| _____ | U.S. Patent Application No. 10/653,624, by McMichael, A. <i>et al.</i> , filed September 2, 2003, Docket No.: 2907.1000-002 |
| _____ | U.S. Patent Application No. 10/833,744, by McMichael, A., <i>eta al.</i> , filed April 28, 2004, Docket No.: 2907.1000-004 |
| _____ | U.S. Patent Application No. 10/833,439, by McMichael, A., <i>et al.</i> , filed April 28, 2004, Docket No.: 2907.1000-005 |
| _____ | U.S. Patent Application No. 10/833,745, by McMichael, A., <i>et al.</i> , filed April 28, 2004, Docket No.: 2907.1000-006 |

Examiner

Date

- [X] A copy of each above-cited application, including the current claims, is enclosed.
- [] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

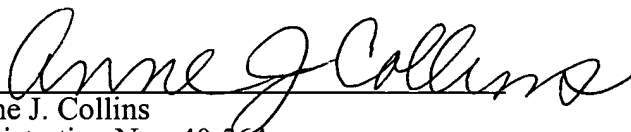
It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,


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Dated:



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| PTO-1449 REPRODUCED | | ATTORNEY DOCKET NO. 2907.1000-003 | | APPLICATION NO. 10/686,943 | |
|  <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>July 2, 2004</p> <p>(Use several sheets if necessary)</p> | | APPLICANT Adrian V.S. Hill, <i>et al.</i> | | | |
| | | FILING DATE October 16, 2003 | | CONFIRMATION NO. 4585 | |

U.S. PATENT DOCUMENTS

| EXAM- INER INI- TIAL | REF. NO. | DOCUMENT NUMBER Number-Kind Code (if known) | ISSUE DATE / PUBLICATION DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
| | AA | 5,110,587 | May 5, 1992 | Paoletti, <i>et al.</i> |
| | AB | 5,185,146 | February 9, 1993 | Altenburger |
| | AC | 5,225,336 | July 6, 1993 | Paoletti |
| | AD | 5,453,364 | September 26, 1995 | Paoletti |
| | AE | 5,766,597 | June 16, 1998 | Paoletti, <i>et al.</i> |
| | AF | 6,663,871 B1 | December 16, 2003 | McMichael, <i>et al.</i> |
| | AG | US-2003-0138454-A1 | July 24, 2003 | Hill, <i>et al.</i> |
| | AH | | | |
| | AI | | | |
| | AJ | | | |
| | AK | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER Country Code-Number-Kind Code (if known) | DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT | TRANSLATION YES NO | |
|--|----|--|--------------------|--|-----------------------|--|
| | AL | WO 97/39771 | October 30, 1997 | The Gov. of the U.S. | | |
| | AM | WO 98/04728 | February 5, 1998 | Therion Biologics Corporation | | |
| | AN | WO 96/26271 | August 29, 1996 | Therion Biologics Corporation | | |
| | AO | | | | | |
| | AP | | | | | |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
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| AR | Ada, G., "Do Cytotoxic T Lymphocytes Clear Some HIV/SIV Infections?," <i>J. Med. Primatol.</i> 25(3):158-162 (June 1996). | |
| AS | Aidoo, M., et al., "Identification of Conserved Antigenic Components For a Cytotoxic T Lymphocyte-Inducing Vaccine Against Malaria," <i>Lancet</i> 345(8956):1003-1007 (Apr. 22, 1995). | |
| AT | Aidoo, M., et al., "Recombinant Vaccinia Viruses for the Characterization of <i>Plasmodium falciparum</i> -specific Cytotoxic T Lymphocytes: Recognition of Processed Antigen Despite Limited Re-Stimulation Efficacy," <i>Intl. Immunol.</i> 9(5):731-737 (Jan. 1997). | |
| AU | Allsopp, C.E.M., et al., "Comparison of Numerous Delivery Systems for the Induction of Cytotoxic T Lymphocytes By Immunization," <i>Eur. J. Immunol.</i> 26:1951-1959 (1996). | |
| AV | Blanchard, T., et al., "Future Vaccines for HIV," <i>Lancet</i> 348(9043):1741 (Dec. 1996). | |
| AW | Blanchard, T.J., et al., "Modified Vaccinia Virus Ankara Undergoes Limited Replication in Human Cells and Lacks Several Immunomodulatory Proteins: Implications for Use as a Human Vaccine," <i>J. Gen. Virol.</i> 79:1159-1167 (1998). | |
| AX | Carroll, M.W., et al., "Highly Attenuated Modified Vaccinia Virus Ankara (MVA) as an Effective Recombinant Vector: A Murine Tumor Model," <i>Vaccine</i> 15(4):387-394 (1997). | |
| AY | Chamberlain, R.S., et al., "Use of Multiple Vaccination Vectors for the Generation of CTL Against a Model Tumor Antigen," <i>Proceedings of the Annual Meeting of the American Association for Cancer Research</i> (Washington, April 20-24, 1996, 37, Abstract No. 3263). | |
| AZ | Doolan, D.L., "The Complexity of Protective Immunity Against Live-Stage Malaria," <i>J. Immunol.</i> , 165(3):1453-1462 (2000). | |
| AR2 | Doolan, D.L., et al., "Circumventing Genetic Restriction of Protection against Malaria with Multigene DNA Immunization: CD8 ⁺ T Cell-, Interferon γ -, and Nitric Oxide-Dependent Immunity," <i>J. Exp. Med.</i> 183(4):1739-1746 (April 1996). | |
| AS2 | Fuller, D.H., et al., "Gene Gun-Based Nucleic Acid Immunization Alone or in Combination with Recombinant Vaccinia Vectors Suppresses Virus Burden in Rhesus Macaques Challenged with a Heterologous SIV," <i>Immunol. Cell Biol.</i> 75(4):389-396 (Aug. 1997). | |

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| AT2 | Fuller, D.H., <i>et al.</i> , "Enhancement of Immunodeficiency Virus-Specific Immune Responses in DNA-Immunized Rhesus Macaques," <i>Vaccine</i> , 15(8):924-926 (June 1997). | |
| AU2 | Gallimore, A., <i>et al.</i> , "Early Suppression of SIV Replication By CD8 ⁺ <i>nef</i> -specific Cytotoxic T Cells In Vaccinated Macaques," <i>Nature Med.</i> 1(11):1167-1173 (Nov. 1995). | |
| AV2 | Gilbert, S.C., <i>et al.</i> , "A Protein Particle Vaccine Containing Multiple Malaria Epitopes," <i>Nat. Biotechnol.</i> , 15(12):1280-1284 (1997). | |
| AW2 | Greenspan, N.S., <i>et al.</i> , "Defining Epitopes: It's Not As Easy As It Seems," <i>Nature Biotechnology</i> 7:936-937 (1999). | |
| AX2 | Hanke, T., <i>et al.</i> , "Immunogenicities of Intravenous and Intramuscular Administrations of Modified Vaccinia Virus Ankara-Based Multi-CTL Epitope Vaccine for Human Immunodeficiency Virus Type 1 in Mice," <i>J. Gen. Virol.</i> 79:83-90 (1998). | |
| AY2 | Hanke, T., <i>et al.</i> , "Enhancement of MHC Class I-Restricted Peptide-Specific T Cell Induction by a DNA Prime/MVA Boost Vaccination Regime," <i>Vaccine</i> 16(5):439-445 (1998). | |
| AZ2 | Hanke, T., <i>et al.</i> , "DNA Multi-CTL Epitope Vaccines for HIV and <i>Plasmodium falciparum</i> : Immunogenicity in Mice," <i>Vaccine</i> 16(4):426-435 (1998). | |
| AR3 | Hill, AV, "DNA-Based Vaccines for Malaria: a Heterologous Prime-Boost Immunisation Strategy," <i>Dev. Biol. (Basel)</i> , 104:171-179 (2000). | |
| AS3 | Hill, A.V.S., <i>et al.</i> , "Common West African HLA Antigens Are Associated With Protection From Severe Malaria," <i>Nature</i> 352(6336):595-600 (Aug. 15, 1991). | |
| AT3 | Hirsch, V.M., <i>et al.</i> , "Patterns of Viral Replication Correlate with Outcome in Simian Immunodeficiency Virus (SIV)-Infected Macaques: Effect of Prior Immunization with a Trivalent SIV Vaccine in Modified Vaccinia Virus Ankara," <i>J. Virol.</i> 70(6):3741-3752 (June 1996). | |
| AU3 | Hodge, J.W., <i>et al.</i> , "Diversified Prime and Boost Protocols Using Recombinant Vaccinia Virus and Recombinant Non-Replicating Avian Pox Virus to Enhance T-Cell Immunity and Antitumor Responses," <i>Vaccine</i> 15(6/7):759-768 (April/May 1997). | |
| AV3 | Tascon, R. <i>et al.</i> , "Vaccination Against Tuberculosis by DNA Injection," <i>Nat. Med.</i> 2: 893-898 (1996). | |

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| AW3 | Irvine, K.R., <i>et al.</i> , "Route of Immunization and the Therapeutic Impact of Recombinant Anticancer Vaccines," <i>J. Natl. Cancer Inst.</i> 89(5):390-392 (March 1997). | |
| AX3 | Irvine, K.R., <i>et al.</i> , "Enhancing Efficacy of Recombinant Anticancer Vaccines With Prime/Boost Regiments That Use Two Different Vectors," <i>J. Natl. Cancer Inst.</i> 89(21):1595-1601 (Nov. 1997). | |
| AY3 | Lalvani, A., <i>et al.</i> , "An HLA-Based Approach to the Design of a CTL-Inducing Vaccine Against <i>Plasmodium falciparum</i> ," <i>Research in Immunology</i> 145(6):461-468 (1994). | |
| AZ3 | Lanar, D.E., <i>et al.</i> , "Attenuated Vaccinia Virus-Circumsporozoite Protein Recombinants Confer Protection against Rodent Malaria," <i>Infect. Immun.</i> 64(5):1666-1671 (May 1996). | |
| AR4 | Layton, F.T., <i>et al.</i> , "Induction of Single and Dual Cytotoxic T-Lymphocyte Responses to Viral Proteins in Mice Using Recombinant Hybrid Ty-Virus-Like Particles," <i>Immunology</i> 87(2):171-178 (Feb. 1996). | |
| AS4 | Leong, K.H., <i>et al.</i> , "Selective Induction of Immune Responses by Cytokines Coexpressed in Recombinant Fowlpox Virus," <i>J. Virol.</i> , 68(12):8125-8130 (Dec. 1994). | |
| AT4 | Leong, K.H., <i>et al.</i> , "Generation of Enhanced Immune Responses by Consecutive Immunization with DNA and Recombinant Fowl Pox Vectors." In <i>Vaccines 95</i> , Cold Spring Harbor Laboratory Press, p.327-331 (1995). | |
| AU4 | Li, Shengqiang, <i>et al.</i> , "Priming With Recombinant Influenza Virus Followed By Administration of Recombinant Vaccinia Virus Induces CD8 ⁺ T-Cell-Mediated Protective Immunity against Malaria," <i>Proc. Natl. Acad. Sci. USA</i> 90(11):5214-5218 (June 1993). | |
| AV4 | Limbach, K.J. and Paoletti, E., "Non-Replicating Expression Vectors: Application in Vaccine Development and Gene Therapy," <i>Epidemiol. Infect.</i> 116:241-256 (1996). | |
| AW4 | Mahnel, <i>et al.</i> , "Experiences with Immunization Against Orthopox Viruses of Humans and Animals Using Vaccine Strain MVA," <i>Berliner Und Munchener Tierarztliche Wochenschrift</i> 107(8):253-256 (1994) ABSTRACT ONLY | |
| AX4 | McMichael, A., <i>et al.</i> , "Malaria and Other Tropical Diseases," <i>Immunol. Letters</i> 56(1/3):28, 425, 291 (June 22-25, 1997)(Abstract Nos. O.4.05.7, P.4.05.08, P.4.01.18 and P.4.01.22). | |

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| | AY4 | McShane, H., <i>et al.</i> , "Enhanced Immunogenicity of CD4 ⁺ T-Cell Responses and Protective Efficacy of a DNA-Modified Vaccinia Virus Ankara Prime-Boost Vaccination Regimen for Murine Tuberculosis," <i>Infect. Imm.</i> 69(2):681-686 (2001). |
| | AZ4 | Moorthy, M.S., <i>et al.</i> , "Safety of DNA and Modified vaccinia virus Ankara Vaccines Against Liver-Stage <i>P. falciparum</i> Malaria in Non-Immune Volunteers," <i>Vaccine</i> , 21(17-18):1995-2002 (2003). |
| | AR5 | Moorthy, M.S. and Hill, A., "Malaria Vaccines," <i>Br. Med. Bull.</i> , 62:59-72 (2002). |
| | AS5 | Moreno, A., <i>et al.</i> , "Cytotoxic CD4 ⁺ T Cells From a Sporozoite-Immunized Volunteer Recognize the <i>Plasmodium falciparum</i> CS Protein," <i>Int-Immunol</i> , 3(10):997-1003 (1991). |
| | AT5 | Moss, B., <i>et al.</i> , "Host Range Restricted, Non-Replicating Vaccinia Virus Vectors as Vaccine Candidates," <i>Advances in Experimental Medicine and Biology</i> 397:7-13 (1996). |
| | AU5 | Müller, H.M., <i>et al.</i> , "Thrombospondin Related Anonymous Protein (TRAP) of <i>Plasmodium falciparum</i> Binds Specifically to Sulfated Glycoconjugates and to HepG2 Hepatoma Cells Suggesting a Role for this Molecule in Sporozoite Invasion of Hepatocytes," <i>Embo J.</i> :2881-2889 (July 1993). |
| | AV5 | Murata, K., <i>et al.</i> , "Characterization of <i>in Vivo</i> Primary and Secondary CD8 ⁺ T Cell Responses Induced by Recombinant Influenza and Vaccinia Viruses," <i>Cell. Immunol.</i> 173(1):96-107 (Oct. 10, 1996). |
| | AW5 | Nardin, E.H. and Nussenzweig, R.S., "T Cell Responses to Pre-Erythrocytic Stages of Malaria: Role in Protection and Vaccine Development Against Pre-Erythrocytic Stages," <i>Annu. Rev. Immunol.</i> 11:687-727 (1993). |
| | AX5 | Plebanski, M., <i>et al.</i> , "Protection From <i>Plasmodium berghei</i> Infection By Priming and Boosting T Cells to a Single Class I-Restricted Epitope with Recombinant Carriers Suitable for Human Use," <i>Eur. J. Immunol.</i> , 28(12):4345-4355 (1998). |
| | AY5 | Richmond, J.F.L., <i>et al.</i> , "Screening of HIV-1 Env Glycoproteins for the Ability to Raise Neutralizing Antibody Using DNA Immunization and Recombinant Vaccinia Virus Boosting," <i>Virology</i> 230:265-274 (1997). |
| | AZ5 | Rodrigues, E.G., <i>et al.</i> , "Single Immunizing Dose of Recombinant Adenovirus Efficiently Induces CD8 ⁺ T Cell-Mediated Protective Immunity Against Malaria," <i>J. Immunol.</i> 158(3):1268-1274 (Feb. 1997). |

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| AR6 | Rodrigues, M., et al., "Influenza and Vaccinia Viruses Expressing Malaria CD8 ⁺ T and B Cell Epitopes," <i>J. Immunol.</i> 153(10):4636-4648 (Nov. 15, 1994). | |
| AS6 | Schneider, J., et al., "A Prime-Boost Immunisation Regimen Using DNA Followed By Recombinant Modified Vaccinia Virus Ankara Induces Strong Cellular Immune Responses Against the <i>Plasmodium falciparum</i> TRAP Antigen In Chimpanzees," <i>Vaccine</i> , 19(32):4595-4602 (2001). | |
| AT6 | Schneider, J., et al., "Induction of CD8 ⁺ T Cells Using Heterologous Prime-Boost Immunisation Strategies," <i>Immunological Reviews</i> , 170:29-38 (1999). | |
| AU6 | Schneider, J., et al., "Enhanced Immunogenicity for CD8 ⁺ T Cell Induction and Complete Protective Efficacy of Malaria DNA Vaccination by Boosting with Modified Vaccinia Virus Ankara," <i>Nature Medicine</i> 4(4): 397-402 (April 1998). | |
| AV6 | Schödel, F., et al., "Immunity to Malaria Elicited by Hybrid Hepatitis B Virus Core Particles Carrying Circumsporozoite Protein Epitopes," <i>J. Exp. Med.</i> 180(3):1037-1046 (Sept. 1994). | |
| AW6 | Sedegah, M., et al., "Protection against Malaria by Immunization with Plasmid DNA Encoding Circumsporozoite Protein," <i>Proc. Natl. Acad. Sci. USA</i> 91(21):9866-9870 (Oct. 1994). | |
| AX6 | Seguin, M.C., et al., "Induction of Nitric Oxide Synthase Protects against Malaria in Mice Exposed to Irradiated <i>Plasmodium berghei</i> Infected Mosquitoes: Involvement of Interferon γ and CD8 ⁺ T Cells," <i>J. Exp. Med.</i> 180(1):353-358 (July 1994). | |
| AY6 | Stoute, J.A., et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against <i>Plasmodium falciparum</i> Malaria," <i>NE J. of Medicine</i> 336:86-91 (1997). | |
| AZ6 | Sutter, G., et al., "A Recombinant Vector Derived From the Host Range-Restricted and Highly Attenuated MVA Strain of Vaccinia Virus Stimulates Protective Immunity in Mice to Influenza Virus," <i>Vaccine</i> 12(11):1032-1040 (Aug. 1994). | |
| AR7 | Tartaglia, J., et al., "NYVAC: A Highly Attenuated Strain of Vaccinia Virus," <i>Virology</i> 188(1):217-232 (May 1992). | |
| AS7 | Tascon, et al., "Immunogenicity and Protective Efficacy of a Tuberculosis DNA Vaccine," <i>Nat. Med.</i> 2: 888-892 (1996). | |

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| AT7 | Tsang, K.Y., <i>et al.</i> , "Generation of Human Cytotoxic T Cells Specific for Human Carcinoembryonic Antigen Epitopes From Patients Immunized With Recombinant Vaccinia-CEA Vaccine," <i>J. Natl. Cancer Inst.</i> 87(13):982-990 (July 1995). | |
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| | APPLICANT Adrian V.S. Hill, et al. | | |
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